WASHINGTON, DC – House Committee on Oversight and Government Reform Ranking Member Darrell Issa (R-CA) and Chairman Edolphus "Ed" Towns (D-NY) today requested information from the Food and Drug Administration (FDA) related to a recent major voluntary recall of popular over-the-counter pediatric medication by McNeil Consumer Healthcare (a subsidiary of Johnson & Johnson), the manufacturer and marketer of well known over-the-counter and prescription pharmaceuticals. Yesterday, Towns and Issa announced the committee's investigation into the circumstances surrounding the recall of more than 40 over-the-counter medications including Children's Tylenol, Infants' Tylenol and Children's Motrin, as Food and Drug Administration (FDA) inspectors were completing a nearly two-week long inspection of McNeil's Fort Washington, Pennsylvania plant where the medication is produced.

This recall was the third major quality-related recall made by McNeil in the last eight months. The first recall occurred in September 2009 when McNeil recalled infant and children's Tylenol products because an inactive ingredient did not meet quality standards. Then, in November 2009, five lots of over-the-counter Tylenol arthritic pain medication were recalled after an unusual moldy, musty, or mildew-like odor in these products caused reports of nausea, stomach pain, vomiting, and diarrhea. This recall was expanded in December 2009 to include all product lots of this medication. This recall was further expanded once again in January 2010 to include a variety of other over-the-counter products.

“Taken together, these recalls point to a major problem in the production of McNeil products,” said Towns and Issa. “Given McNeil’s questionable track record and consecutive recalls, we need to understand what prior actions the FDA took to address McNeil’s quality control problems and what events led the FDA to its April 2010 inspection of McNeil’s Fort Washington plant.”

It has been reported that FDA has been working with McNeil since May 2009 to address its manufacturing problems. According to one report, FDA met with McNeil in February to express its concerns about McNeil’s production practices and had assured FDA that it was addressing its problems. A clarification of the timing of the events that spurred the recall is important in understanding both McNeil’s and FDA’s response to the problem.

FDA’s most alarming finding was that raw materials used to make these infant and children’s products were contaminated with potentially harmful bacteria. According to FDA, the bacteria have not been found in any finished product and no illnesses or deaths have been reported.

Towns and Issa said, “We are deeply concerned about the recall of popular pediatric medications that millions of families have grown to rely on and stocked in their medicine cabinets. A recall of this nature, especially when it involves children, calls for swift action and cooperation from all parties. We look forward to receiving the FDA’s response to our inquiry. The American people deserve answers and we intend to get to the bottom of this matter.”

Text of the letter is included below.

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May 6, 2010

The Honorable Margaret A. Hamburg, M.D.

Commissioner

U.S. Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20857

Dear Dr. Hamburg:

We are writing in regard to the recent recall of popular over-the-counter pediatric products. On April 30, 2010, McNeil Consumer Healthcare, a subsidiary of Johnson & Johnson, recalled over 40 variations of infant and children's liquid products after a Food and Drug Administration (FDA) inspection uncovered concerns surrounding the quality, purity, and potency of the products. Brands affected by this recall include Tylenol, Motrin, Zyrtec, and Benadryl products.

The FDA inspection of McNeil's Fort Washington, Pennsylvania, plant uncovered several alarming deficiencies in the manufacturing of these products. For instance, FDA found that McNeil did not properly test its products, did not properly train its employees, failed to maintain equipment, and lacked other important quality controls. FDA also found that McNeil failed to sufficiently investigate problems in its manufacturing and in its drugs.

However, FDA's most alarming finding was that raw materials used to make these infant and children's products were contaminated with potentially harmful bacteria. Thankfully, according to FDA, the bacteria have not been found in any finished product and no illnesses or deaths have been reported.

This recall was the third major recall made by McNeil in the last eight months due to quality problems. The first recall occurred in September 2009 when McNeil recalled infant and children's Tylenol products because an inactive ingredient did not meet quality standards. Then, in November 2009, five lots of over-the-counter Tylenol arthritis pain medication were recalled after an unusual moldy, musty, or mildew-like odor in these products caused reports of nausea, stomach pain, vomiting, and diarrhea. This recall was expanded in December 2009 to include all product lots of this medication. This recall was further expanded in January 2010 to include a variety of other over-the-counter products.

Taken together, these recalls point to a major problem in the production of McNeil products, and raise questions as to the adequacy of FDA's response to repeated problems with McNeil's manufacturing practices. It has been reported that FDA has been working with McNeil since May 2009 to address its quality problems. According to one report, FDA met with McNeil in February to express its concerns about McNeil's production practices and had assured FDA that it was addressing its problems. A clarification of the timing of the events that spurred the recall is important in understanding both McNeil's and FDA's response to the problem.

The Committee on Oversight and Government Reform is the principal oversight committee in the U.S. House of Representatives, with jurisdiction over "any matter." Under Rules X and XI of the Rules of the House of Representatives, the Committee is investigating the recent recall of over-the-counter pediatric products. To assist the Committee in its investigation, we request that you provide the following information and records:

1. What prompted FDA's April 2010 inspection of McNeil's Fort Washington plant? For example, was this a "for cause" inspection or was this a routine current good manufacturing practice (cGMP) inspection as required by statute?

2. Please provide copies of all records, in an unredacted form, relating to inspections of all McNeil Consumer Healthcare manufacturing facilities, including Form 483s and Establishment Inspection Reports, since January 1, 2008.

3. Please identify the bacteria that were found in the raw materials at McNeil's Fort Washington plant in April 2010. Were any raw materials at this plant adulterated or contaminated in any way besides the reported bacteria contamination?

4. Please identify the supplier or suppliers of the raw materials in which bacteria or any other contamination or adulteration was found at McNeil's Fort Washington plant in April 2010.

5. If any of the contaminated or adulterated raw materials used by this facility came from foreign sources, please identify those foreign facilities and indicate when FDA last inspected them.

6. Please provide a chronology of events from January 1, 2008, through April 30, 2010, that led to the McNeil recalls in September 2009, November 2009, December 2009, January 2010, and April 2010.

7. Please provide copies of all complaints or adverse events associated with any McNeil product since January 1, 2008.

We also request that you brief Committee staff on the status of your investigation as soon as possible.

Please deliver the requested information and records to the Committee on Oversight and Government Reform, room 2157 Rayburn House Office Building, no later than 4:00 p.m. on Monday, May 17, 2010. To facilitate delivery and review, we prefer that the records be delivered in digital form. Please note that the terms “records” and “relating to” are defined in the attachment to this letter.

Should you or your staff have any questions with regard to this request, please contact Majority staff at (202) 225-5051 or the Minority staff at (202) 225-5074.

Sincerely,

Edolphus Towns

Chairman

Darrell Issa

Ranking Member